

## REMARKS

Claims 1-26 are pending in this application. Claims 13 and 15-17 have been withdrawn from consideration. By this Amendment, claims 1, 14 and 18 have been amended. Support for the amendments is found, for example, from paragraphs [0023] and [0024] of the specification and Figs. 2A-4. No new matter is introduced by this Amendment.

The drawings are objected to under 37 C.F.R. §1.84(l) as containing lines, numbers and letters not uniformly thick and well defined. Applicants submit herewith a copy of corrected drawings, to overcome the objection.

The Examiner has rejected claims 1-9, 11, 12 and 14 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5, 749, 828 to Solomon et al. (hereafter "Solomon"). The rejection is respectfully traversed.

Applicants' independent claim 14 recites a unitary element for use in a variable stiffness malleable shaft. Applicants' independent claim 1 recites a variable stiffness malleable shaft comprising a plurality of unitary shaft elements. The unitary shaft element of claims 1 and 14 comprises, *inter alia*, a generally prismatic body defining a first longitudinal axis, a plurality of axial through holes, a recess formed in a proximal end of the element and a protrusion formed in a distal end of the element. The recess is defined along a second axis transverse to the first longitudinal axis. The protrusion is defined along a third axis transverse to the longitudinal axis. The second and third axes are oriented relative to one another such that the respective axial through holes of adjacent shaft elements are aligned with one another when a protrusion of one shaft element is aligned with a recess in an adjacent, like shaft element.

Solomon discloses a bending neck for use with invasive medical devices. The bending neck is constructed by a series of links (2) and sleeves (12) assembled together. Specifically, the link (2) is provided with a plurality of tabs (4) along a rim of the link (see Figs. 2A and 2B of Solomon). The sleeve (12) is provided with a plurality of sockets (19) engaging the tabs

(4). Thus, when the sleeve slides over the link, the sleeve is engaged and held in place by the tabs, to realize an assembled element of the bending neck.

In contrast, the present invention, as recited in claims 1 and 14, discloses a unitary element for use in a variable stiffness malleable shaft. Since Solomon only discloses a bending neck constructed by a series of assembled elements, Solomon fails to disclose the unitary shaft element recited in claims 1 and 14. Thus, Solomon fails to disclose the combination of features recited by claims 1 and 14. Further, there is no teaching, suggestion, motivation or reasoning in Solomon to modify the Solomon assembled element to arrive at the unitary element of the present invention.

Thus, the rejection of claims 1-9, 11, 12 and 14 under 35 U.S.C. §103(a) over Solomon is overcome and withdrawal thereof is respectfully requested.

The Examiner has rejected claim 10 under 35 U.S.C. §103(a) as allegedly unpatentable over Solomon in view of U.S. Patent No. 6,364,828 to Yeung et al. (hereafter “Yeung”). The rejection is respectfully traversed.

Claim 1, from which claim 10 depends, is discussed above. Solomon is discussed above relative to claim 1. Yeung is relied on to allegedly teach the additional features of claim 10. Yeung does not overcome the underlying deficiencies of Solomon. Thus, the combination of Solomon and Yeung does not arrive at the combination of features recited in claim 1, from which claim 10 depends. Further, there is no teaching, suggestion, motivation or reasoning in Yeung to modify Solomon or Yeung to arrive at the combination of features recited in claim 1.

Thus, the rejection of claim 10 under 35 U.S.C. §103(a) based on the combination of Solomon and Yeung is overcome and withdrawal thereof is respectfully requested.

The Examiner has rejected claims 18-22 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,381,782 to DeLaRama et al. (hereafter “DeLaRama”). The rejection is respectfully traversed.

Claim 18 recites a variable stiffness malleable shaft. The shaft comprises a pair of tension elements, a fulcrum having a distal side and a proximal side, an actuator for applying force to the tension elements, and a connector linking the fulcrum to the actuator. Significantly, each tension member is connected at the distal end thereof to a distal end of the malleable shaft and at the proximal end thereof to the other tension element, and the joined proximal ends of the tension elements pass over the proximal side of the fulcrum.

DeLaRama discloses a bi-directional or multi-directional miniscope. The miniscope comprises a proximal end connected to a control assembly and a distal end connected to a spring frame. Two or more activation wires extend longitudinally through the miniscope, and are connected at one end thereof to the spring frame and at the other end thereof to the control assembly. The activation wires can be activated by the control assembly to change the orientation of the spring frame, thus to realize a bi-directional or multi-directional miniscope. Specifically, as shown in Figs. 9-11 thereof, DeLaRama discloses a multi-directional miniscope having three activation wires (76). The control assembly (18a) of this embodiment comprises a housing portion (24a) and a handle member (24a). The handle member comprises a ball portion (80) seated in the housing portion (24a). The proximal ends of each of the three activation wires (76) are attached to a ball portion (80) of the handle member (24a) (see Fig. 10 of DeLaRama).

In contrast, the present invention, as recited in claim 18, discloses a malleable shaft having a pair of tension members, wherein the proximal ends of the tension members are connected with each other to pass over the proximal side of the fulcrum (ball portion (80) of DeLaRama). As illustrated in Fig. 10 of DeLaRama, the ends of the three activation wires are separately attached, through an opening formed at the lower side of the ball portion (80), to the inner side of the ball portion (80). The ends of the wire are not connected to each other and none of the wires pass over the ball portion.

Thus, DeLaRama fails to disclose the combination of features recited by claims 18, from which claims 19-22 depend. Further, there is no teaching, suggestion, motivation or any reasoning in DeLaRama to modify the DeLaRama miniscope to arrive at the variable stiffness malleable shaft of the present invention, as recited in claim 18.

Therefore, the rejection of claims 18-22 under 35 U.S.C. §103(a) based on DeLaRama is overcome and withdrawal thereof is respectfully requested.


The Examiner has rejected claims 23-26 under 35 U.S.C. §103(a) as allegedly unpatentable over DeLaRama in view of Yeung. The rejection is respectfully traversed.

Claim 18, from which claims 23-26 depend, is discussed above. DeLaRama is discussed above relative to claim 18. Yeung is relied on to allegedly teach the additional features of claims 23-26. Yeung does not overcome the underlying deficiencies of DeLaRama. Thus, the combination of DeLaRama and Yeung does not arrive at the combination of features recited in claim 18, from which claims 23-26 depend. Further, there is no teaching, suggestion, motivation or reasoning in Yeung to modify DeLaRama or Yeung to arrive at the combination of features recited in claim 18.

Thus, the rejection of claims 23-26 under 35 U.S.C. §103(a) based on the combination of DeLaRama and Yeung is overcome and withdrawal thereof is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited

Respectfully submitted,



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